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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,079	07/02/1999	JACQUES R. FRESCO	960-219US	4709

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EXAMINER
BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/341,079	LAVELLE ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 March 2003 has been entered.

Specification

2. The objection to the specification in the Office action mailed 12 March 2002 is withdrawn in view of the amendment entering an abstract to the specification filed 10 March 2003.

Claim Objections

3. The objection to claims 31 and 32 in the Office action mailed 12 March 2002 is withdrawn in view of the amendment filed 10 March 2003.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing stability of triplex nucleic acids in an isolated

solution, does not reasonably provide enablement for a method for enhancing stability of triplex nucleic acids within a living cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In In re Wands (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the full scope of the claimed invention one of skill in the art must make and use triplex nucleic acids within a cell whose stability is enhanced by addition of a water structure-making substance to the triplex nucleic acid within a cell. For the reasons discussed below, there would be an unpredictable amount of experimentation required to make and use the claimed invention.

b) The specification presents no specific guidance for using the claimed method within a cell. The specification defines the term "solution" on page 5 of the instant specification as including both in vitro and in vivo environments

c) The specification presents no working examples for using the claimed method within a cell.

d) The invention is drawn to a method for enhancing stability of triplex nucleic acids within a living cell.

e) A review of the prior art does not reveal publications that provide guidance or working examples to practice the claimed method of enhancing stability of triplex nucleic acids within a cell.

f) The skill of those in the art of triplex nucleic acids is high.

g) The prior art is silent on the predictability of practicing the claimed invention within a cell.

h) The claims are broad in that they are drawn to methods of enhancing stability of triplex nucleic acids within a living cell by addition of a wide range of water structure-making substances to the cell, without any guidance as to how to add such water structure-making substances to a living cell, and without evidence that addition of such water structure-making substances would be effective and non-toxic to the cell if added to the cell.

The skilled practitioner would first turn to the instant specification for guidance in practicing the full scope of the claimed invention. However, the specification does not provide guidance or working examples to practice the claimed method within a living cell. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not show use of the claimed method within a living cell. Finally, said practitioner would turn to trial and error experimentation to practice the claimed method within a living cell. Such represents undue experimentation.

6. Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive. The applicants point to guidance on page 5, lines 3-11 for support for enablement.

However the pointed to passage merely gives general guidance to use cationic lipids to perform the claimed method in vivo. This does not constitute sufficiently specific guidance to overcome the lack of other guidance in the specification or the prior art to practice the full scope of the claimed methods on living cells that is detailed in the above rejection.

7. The rejection of claims 1-15, 31, and 32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the Office action mailed 12 March 2002 is withdrawn in view of the amendment filed 10 March 2003.

8. The rejection of claim 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office action mailed 12 March 2002 is withdrawn in view of the amendment filed 10 March 2003.

Claim Rejections - 35 USC § 102

9. The rejection of claims 1, 2, 4, 5, 9, 14, 16, 17, 19, 20, 24, 29, 31, and 32 under 35 U.S.C. 102(b) as being anticipated by Kiyama et al. in the Office action mailed 12 March 2002 is withdrawn in view of the arguments and amendment filed 10 March 2003.

10. The rejection of claims 1, 7, 8, 14-16, 22, 23, and 29-32 under 35 U.S.C. 102(b) as being anticipated by Shimizu et al. in the Office action mailed 12 March 2002 is withdrawn in view of the arguments and amendment filed 10 March 2003.

11. The rejection of claims 1, 6, 14, 16, 21, 29, 31, and 32 under 35 U.S.C. 102(b) as being anticipated by Spink et al. in the Office action mailed 12 March 2002 is withdrawn in view of the arguments and amendment filed 10 March 2003.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 11-16, and 26-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Moser et al..

The claims are drawn to a method of stabilization of a triplex nucleic acid by addition of ethanol or a cation that is not an alkali or alkaline earth metal cation.

Moser et al. shows use of hexamine cobalt cations (a transition metal) and 40% ethylene glycol to enhance the stability of triplex nucleic acids comprising derivatized nucleotides, detailed in Figure 5A and the second column of page 648.

14. Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive. The applicants state that some details of the effect of the procedure described in Moser are not shown in Moser et al. Nevertheless Moser shows the steps of the claimed method and therefore anticipates the claimed method. To clarify that Moser meets the limitations of use of a water structure making substance of at least 1 molar, the following calculation is provided to show that the 40% solution of ethylene glycol of Moser et al. is equivalent to 7.17 molar (see

attached printout from the Sigma Aldrich catalog showing a density of 1.113 g/ml and a molecular weight of 62.07 g/mole for ethylene glycol).

(400 ml/l) x (1.113g/ml) x (1 mole/62.07g) = 7.17M

Conclusion

15. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

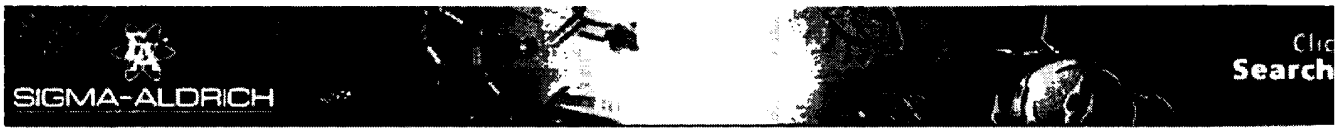
John S. Brusca

Primary Examiner

Art Unit 1631

jsb

April 20, 2003



Product Number: **03747**

Product Name: **Ethylene glycol**

Description
Certificate of Analysis
MSDS
FT-IR Condensed Phase Structure Image

Options

Print Preview
Bulk Quote
Ask A Scientist

Synonyms: 1,2-Ethanediol

Glycol

MDL number: MFCD00002885

Molecular Formula: $C_2H_6O_2$

Molecular Weight: 62.07

CAS Number: 107-21-1

MDL Number: MFCD00002885

Assay: ≥99.5% (GC)

EC Number: 2034733

BRN: 505945

Merck Index: *Merck* **13**,3832

Beilstein Index: *Beil.* **1**,IV.2369

Fieser Index: *Fieser* **1**,375; **5**,296; **9**,217; **15**,156

R&S: : R: 22

Literature References:

1. J.-p. Li, S. Hjertén, *J Biochem. Biophys. Meth.* **22**, 311 (1991)
2. P.-L. Lim, *Mol. Immunol.* **24**, 11 (1987)
3. K. Jung, K.D. Grützmann, *Clin. Biochem.* **21**, 53 (1988)

Comments:

BioChemika Ultra, ≥99.5% (GC)

For desorption in immuno-affinity chromatography: Additive for the stabilization of urinary enzymes

Extended specifications	
Free acid (as CH_3COOH)	≤0.002%
Water	≤0.1%
Insoluble matter	passes filter test
n /D	1.431
bp	195-197 °C
mp	-13--11 °C
Density	1.113 g/mL
Chloride (Cl)	≤10 mg/kg
Sulfate (SO_4)	≤10 mg/kg
Al	≤0.5 mg/kg
As	≤0.1 mg/kg

h g ch c cg b h b e h h ge f g e

Ba	≤0.1 mg/kg
Bi	≤0.1 mg/kg
Ca	≤0.5 mg/kg
Cd	≤0.05 mg/kg
Co	≤0.02 mg/kg
Cr	≤0.02 mg/kg
Cu	≤0.02 mg/kg
Fe	≤0.1 mg/kg
K	≤0.5 mg/kg
Li	≤0.1 mg/kg
Mg	≤0.1 mg/kg
Mn	≤0.02 mg/kg
Mo	≤0.1 mg/kg
Na	≤1 mg/kg
Ni	≤0.02 mg/kg
Pb	≤0.1 mg/kg
Sr	≤0.1 mg/kg
Zn	≤0.1 mg/kg
260 nm	0.03
280 nm	0.01

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h g ch c cg b h b e h h ge f g e